REMARKS

Claims 4-6 and 18-22 are pending in the application. Claims 4-6 and 18-22 are rejected. No claims are allowed.

New claim 23 has been added directed to an embodiment of claim 4 wherein the stopper can be removed from the contact area after the stopper has contacted the distal wall of the barrel. Support for the amendment can be at least in Figures 6-9 of the specification as originally filed. Accordingly, no new matter has been introduced by these amendments.

Claims 4-6 and 18-23 are presented for further proceedings. Reconsideration of the claim rejections and allowance of the pending claims in view of the amendments above and the following remarks are respectfully requested.

Claim Rejections – 35 U.S.C. § 103

a. Claims 4-6 and 22 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Greenwood; US 5,120,314 ("Greenwood") in view of Lynn, US 6,228,065 ("Lynn I"). Regarding claim 4, the Examiner states that Greenwood discloses an I.V. flush syringe assembly comprising a barrel (10) having an inside surface defining a chamber for retaining fluid, an open proximal end (near 15) and a distal end (near 13) including a distal wall with an elongate tip (wall 13, tip 21) extending distally therefrom having a passageway therethrough in fluid communication with said chamber, said inside surface further including a contact area at the distal end of the barrel (Figs. 1, 3 and 6 disclose that the contact area is the area 50 at the distal end of the barrel), a plunger (30) including an elongate body portion (32) having a proximal end (near 35), a distal end (near 36) and a flexible stopper (40) slidably positioned in fluid tight engagement with

said inside surface of said barrel for drawing fluid into and driving fluid out of said chamber by movement of said stopper relative to said barrel, said elongate body portion extending outwardly from said open proximal end of said barrel (Fig. 1), wherein said contact area has a higher coefficient of friction than said inside surface outside of said contact area for frictionally engaging said stopper when said stopper is in contact with said distal wall of said barrel for frictionally holding said stopper in a partially deflected position to prevent reflux of the fluid back into the chamber after fluid has been delivered from said chamber (Figs. 1-10 disclose that the inside surface of the barrel at area 50 has a portion with multiple tabs such as 67 in Fig. 6 and 82 in Fig. 10, wherein the tabs are discontinuous with the inner surface of the barrel and therefore provide an area of higher coefficient of friction). The tabs engage with the plunger 42 as seen in Fig. 10, and col. 5, lines 39-45 disclose that the tabs "dig into the elastic piston 40" which therefore indicates that the digging in of the tabs partially deforms/deflects the piston, and this action keeps the piston at the distal end of the barrel preventing reflux of fluid, wherein the diameter of the outer surface of each portion of the stopper is less than or equal to the largest diameter of the inside surface of the distal end of the barrel having the contact area when the stopper is in the partially deflected position (Fig. 10 discloses that the outside diameter of 42 is equal to or less than the diameter of the interior surface of the barrel wall).

The Examiner acknowledges that Greenwood does not disclose that the contact surface on the inside surface of the barrel is integral, but states that Lynn I discloses a contact surface on an interior surface of the syringe barrel (Fig. 13, projections 220/278) which is integral with the surface of the barrel (claim 19 states that it is integral).

Therefore, according to the Examiner, it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Greenwood's contact area by making it integral with the inside surface of the barrel, as taught by Lynn I, in order to make sure that the contact area does not accidentally become dislodged/break away from the inside surface and therefore render the device's protection system useless. Also, according to the Examiner, it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art.

Applicants respectfully traverse this basis for rejection.

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. *See In re Fine*, 837 F.2d 1071, 1073 (Fed. Cir. 1988). In so doing, the Examiner must make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966), *viz.*, (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the art. "[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). To establish a *prima facie* case of obviousness, all the claim limitations must be taught or suggested by the prior art. *See In re Royka*, 490 F.2d 981, 985 (CCPA 1974). Furthermore, although the analysis need not identify explicit teachings directed to the claimed subject matter, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). As such, "'there must be some articulated reasoning with some rational underpinning to support the legal

conclusion of obviousness.'" *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

Claim 4 (and thus claims 5, 6 and 22 dependent therefrom) is directed to an I.V. flush syringe assembly comprising, *inter alia*, a barrel having an inside surface defining a chamber for retaining fluid, the inside surface integrally including a contact area at the distal end of the barrel which has a higher coefficient of friction than the inside surface of the barrel outside of the contact area for frictionally engaging the stopper and holding it in a partially deflected position to prevent reflux of fluid after the fluid has been delivered from the chamber. In this way, the contact area restrains the compressed stopper from moving in the proximal direction without any need for mechanical interference. *See, e.g.*, Figure 9. In the preferred embodiments recited in claims 5 and 6, the contact area includes a plurality of annular deformations, which can be annular projections on the inside surface of the barrel. *See, e.g.*, Figure 8.

In their previous submission, Applicants explained that annulus 50 in Greenwood is not integral with the syringe barrel, but rather bonded thereto. Although the Examiner acknowledges this, the Examiner now believes that it would have been obvious to provide annulus 50 integrally with the inside surface of syringe barrel, as suggested by Figure 13 of Lynn I. According to Lynn I, detents 220 are provided along the barrel for retaining the distal stopper in a distal venting position. *See* col. 19, lines 10-14. However, contrary to the Examiner's assertion, nothing in Lynn I suggests that the detents are integral with the barrel. Rather, Lynn I states that drug vial 250 in Figure 13 is integral with handle 234. *See* col. 19, line 12. Furthermore, although claim 19, pointed to by the Examiner, states that the "contact member is integral with said conduit," there is

no indication that the contact member is detents 220 in Figure 13. Indeed, it is unclear exactly what the "contact member" is in Lynn I, since that term does not appear in the Detailed Description. Also, the Examiner has not demonstrated that the detents in Lynn I would function to frictionally holding the stopper in a partially deflected position to prevent reflux of the fluid back into the chamber.

In addition, Applicants submit that the Examiner has failed to adequately explain why one of skill in the art would have sought to modify the annulus of Greenwood in the first place. According to the Examiner, it would have been obvious to have modified Greenwood's contact area by making it integral with the inside surface of the barrel, as taught by Lynn I, in order to make sure that the contact area does not accidentally become dislodged/break away from the inside surface and therefore render the device's protection system useless. However, Greenwood teaches that once piston 40 reaches funnel end 20, it cannot be withdrawn because the front edges of locking tabs 52 of annulus 50 now dig into elastic piston 40. Any attempt to move locking tabs 52 in the proximal direction is prevented because anchoring tabs 53 dig into the plastic syringe wall 14 and prevent proximal movement. *See* col. 5, lines 39-44. If the annulus were somehow made integral with the barrel, there would be no anchoring tabs to dig into the barrel wall and prevent proximal movement. Surely, one of skill in the art would not seek to replace a perfectly functioning locking mechanism with an integral structure which would likely lack that function (or at least not function as well). Indeed, it is not clear that providing an integral annulus is even possible, and thus it appears that there is no enabling process for providing the structure contemplated by the Examiner.

Regarding new claim 23, directed to syringe assembly of claim 4 wherein the stopper can be removed from the contact area after the stopper has contacted the distal wall of the barrel, Applicants note that the annulus in Greenwood and the detents in Lynn I are taught as locking mechanisms. As such, neither reference teaches or suggests a contact area from which the stopper can be removed.

Accordingly, Applicants submit that claims 4-6 and 22 (as well as new claim 23) are not unpatentable over Greenwood in view of Lynn I, and reconsideration of this basis for rejection is respectfully requested.

b. Claims 18-20 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Greenwood in view of Lynn, US 5,522,804 ("Lynn II"). According to the Examiner, Greenwood discloses the device substantially as claimed except for a tip cap and flush, but states that Lynn II, discloses a flushing syringe (Figs. 13 and 7c) with a tip cap (Fig. 7c, 124) and flushing solution in the chamber of the syringe, wherein the flushing solution is saline (Fig. 7c, 130; Fig. 7c) discloses that the syringe obtains the flush solution, saline (130) from the pouch by drawing it into the chamber area (seen in Fig. 7c as area 26), and better described by Col. 14, lines 20-30. Thus, according to the Examiner, it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Greenwood with a cap and the use of saline solution, as taught by Lynn II, in order to seal the end of the syringe and to provide the syringe with a flushing solution.

Applicants respectfully traverse this basis for rejection.

Claims 18-20 depend from claim 4. As discussed above with respect to the rejection of claim 4, Greenwood does not disclose the claimed contact area integral with

the inside surface of the barrel. Furthermore, the Examiner has pointed to nothing in Lynn II that remedies the deficiencies of Greenwood in this respect. As such, the combination of Lynn II with Greenwood would not have rendered the claimed invention obvious. *See In re Rijckaert*, 9 F.3d 1531, 1533 (Fed Cir. 1993).

Accordingly, Applicants submit that claims 18-20 are not unpatentable over Greenwood in view of Lynn II, and reconsideration of this basis for rejection is respectfully requested.

CONCLUSION

It is believed that claims 4-6 and 18-23 are now in condition for allowance, early notice of which would be appreciated. No fees are believed due at this time. If any fees are due, the Commissioner is authorized to charge Deposit Account No. 50-3329. Please contact the undersigned if any further issues remain to be addressed in connection with this submission.

Respectfully submitted,

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